DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION

Complete and Return Only the Original Form to: Food and Drug Administration

Form Approved: OMB No. 0910-0387

1. TODAY'S DATE (mm/dd/vyvy)

Center for Devices & Radiological Health, HFZ- 308 Expiration Date: April 30, 2008 **DEVICE LISTING** 9200 Corporate Blvd., Rockville, MD 20850-4015 NOTE: This form is authorized by Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360). Failure to report this information is a violation of Section 301(p) of the Act (21 U.S.C.331(p)). Persons who violate this provision may, if convicted, be subject to a fine or imprisonment or both. The submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2), (21 U.S.C. 331(q)(2)) and may be a violation of 18 U.S.C. 1001. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. 2. OWNER/OPERATOR NUMBER 4. REGISTRATION NUMBER 3. OWNER/OPERATOR NAME (Business name) 5. ESTABLISHMENT NAME (Business name) NUMBER AND STREET NUMBER AND STREET STATE CITY STATE ZIP CODE CITY ZIP CODE POSTAL CODE POSTAL CODE COUNTRY FOREIGN STATE COUNTRY **FOREIGN STATE** 6. LISTING INFORMATION: Number of product codes you are going to list for this establishment REASON FOR LISTING: Update to Device Already Listed Delete Listing REASON FOR LISTING: New Listing Update to Device Already Listed New Listing Delete Listing PRODUCT CODE PMA NUMBER 510(k) NUMBER PRODUCT CODE PMA NUMBER 510(k) NUMBER CLASSIFICATION NAME CLASSIFICATION NAME PROPRIETARY NAME PROPRIETARY NAME COMMON OR USUAL NAME COMMON OR USUAL NAME PREVIOUS LISTING NUMBER LISTING NUMBER PREVIOUS LISTING NUMBER LISTING NUMBER Contract Manufacturer Reprocessor of Single Use Devices Contract Manufacturer Manufacturer Reprocessor of Single-use device Manufacturer Contract Sterilizer Remanufacturer Specification Developer Contract Sterilizer Remanufacturer Specification Developer Foreign Exporter Repackager/Relabeler U.S. Manufacturer of Export Only Devices Foreign Exporter Repackager/Relabeler U.S. Manufacturer of Export Only Devices REASON FOR LISTING: **REASON FOR LISTING:** New Listing Update to Device Already Listed Delete Listing New Listing Update to Device Already Listed Delete Listing PRODUCT CODE PMA NUMBER 510(k) NUMBER PRODUCT CODE PMA NUMBER 510(k) NUMBER CLASSIFICATION NAME **CLASSIFICATION NAME** PROPRIETARY NAME PROPRIETARY NAME COMMON OR USUAL NAME COMMON OR USUAL NAME PREVIOUS LISTING NUMBER LISTING NUMBER PREVIOUS LISTING NUMBER LISTING NUMBER Contract Manufacturer Manufacturer Reprocessor of Single Use Devices Contract Manufacturer Manufacturer Reprocessor of Single Use Devices Contract Sterilizer Remanufacturer Specification Developer Contract Sterilizer Remanufacturer Specification Developer Foreign Exporter Repackager/Relabeler U.S. Manufacturer of Export Only Devices Foreign Exporter Repackager/Relabeler U.S. Manufacturer of Export Only Devices 7. SIGNATURE OF OFFICIAL CORRESPONDENT 8. TYPED OR PRINTED NAME TITLE